

(f) *Content statement.* All reference to hexachlorophene limit in this order is on a weight-in-weight (w/w) basis. Quantitative declaration of hexachlorophene content on the labeling of the products, where required, shall be on a w/w basis.

(g) *Shipments of products.* Shipments of products falling within the scope of paragraphs (c), (d), or (e) of this section which are not in compliance with the guidelines stated herein shall be the subject of regulatory proceedings after the effective date of the final order.

(h) *Prior notices.* This order preempts any conditions for marketing products set forth in the following prior notices.

1. DESI No. 4749 (34 FR 15389, October 2, 1969), "Certain OTC Drugs for Topical Use."

2. DESI No. 2855 (35 FR 12423, August 4, 1970), "Certain Mouthwash and Gargle Preparations."

3. DESI No. 8940 (36 FR 14510, August 6, 1971), "Topical Cream Containing Ppyrilamine Maleate, Benzocaine, Hexachlorophene, and Cetrimonium Bromide."

4. DESI No. 6615 (36 FR 18022, September 8, 1971), "Deodorant/Antiperspirant."

5. DESI No. 6270 (36 FR 23330, December 8, 1971), "Certain Preparations Containing Hexachlorophene".

[40 FR 14033, Mar. 27, 1975, as amended at 42 FR 63773, Dec. 20, 1977; 55 FR 11577, Mar. 29, 1990]

PART 290—CONTROLLED DRUGS

Subpart A—General Provisions

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AUTHORITY: Secs. 502, 503, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 353, 355, 371).

SOURCE: 40 FR 14040, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 290.5 Drugs; statement of required warning.

The label of any drug listed as a "controlled substance" in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." This statement is not required to appear on the label of a controlled substance dispensed for use in clinical investigations which are "blind."

§ 290.6 Spanish-language version of required warning.

By direction of section 305(c) of the Federal Controlled Substances Act, § 290.5, promulgated under section 503(b) of the Federal Food, Drug, and Cosmetic Act, requires the following warning on the label of certain drugs when dispensed to or for a patient: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." The Spanish version of this is: "Precaucion: La ley Federal prohíbe el transferir de esta droga a otra persona que no sea el paciente para quien fue recetada."

§ 290.10 Definition of emergency situation.

For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the Federal Controlled Substances Act, the term *emergency situation* means those situations in which the prescribing practitioner determines:

(a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, and

(c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Subpart B—[Reserved]

Subpart C—Requirements for Specific
Controlled
Drugs—[Reserved]PART 291—DRUGS USED FOR
TREATMENT OF NARCOTIC AD-
ICTS

Sec.

291.501 Narcotic drugs in the maintenance treatment of narcotic addicts.

291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

AUTHORITY: Secs. 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; secs. 301(d), 548, 1976 of the Public Health Service Act (42 U.S.C. 241(d), 290ee-3, 300y-11); 42 U.S.C. 257a.

§ 291.501 Narcotic drugs in the maintenance treatment of narcotic addicts.

(a) The Food and Drug Administration, the National Institute on Drug Abuse, and the Drug Enforcement Administration, Department of Justice, recognize that the use of narcotic drugs in the prolonged maintenance of narcotic dependence has been shown to be an effective part of a total treatment effort in the management and rehabilitation of selected narcotic addicts. It is also recognized that a number of dangers and possible abuses may arise from such efforts if professional services and controls are inadequately applied.

(b) Therefore, the Commissioner of Food and Drugs, the Director of the National Institute on Drug Abuse, and the Administrator of the Drug Enforcement Administration, Department of Justice, agree that interested professionals, municipalities, and organizations should be allowed to use narcotic drugs in the medical treatment of narcotic addiction within a framework of adequate controls designed to protect the individual patients and the community. Narcotic drugs that are to be used as part of the treatment of narcotic addiction must have an approved new

drug application for such use. To facilitate this purpose, the Food and Drug Administration, the National Institute on Drug Abuse, and the Drug Enforcement Administration, Department of Justice, have jointly agreed upon acceptable conditions for the use of narcotic drugs in a treatment program, which are set forth in § 291.505. In addition, such other provisions of the Federal narcotic laws and regulations as are applicable must also be observed.

[58 FR 38709, July 20, 1993]

§ 291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(a) *Definitions.* As used in this part:

(1) *Detoxification treatment* means the dispensing of a narcotic drug in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period. There are two types of detoxification treatment: short-term detoxification treatment and long-term detoxification treatment.

(i) *Short-term detoxification treatment* is for a period not in excess of 30 days.

(ii) *Long-term detoxification treatment* is for a period more than 30 days but not in excess of 180 days.

(2) *Maintenance treatment* means the dispensing of a narcotic drug, at relatively stable dosage levels, in the treatment of an individual for dependence on heroin or other morphine-like drug. There are two types of maintenance treatment: comprehensive maintenance treatment and interim maintenance treatment.

(i) *Comprehensive maintenance treatment* is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

(ii) *Interim maintenance treatment* is maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting